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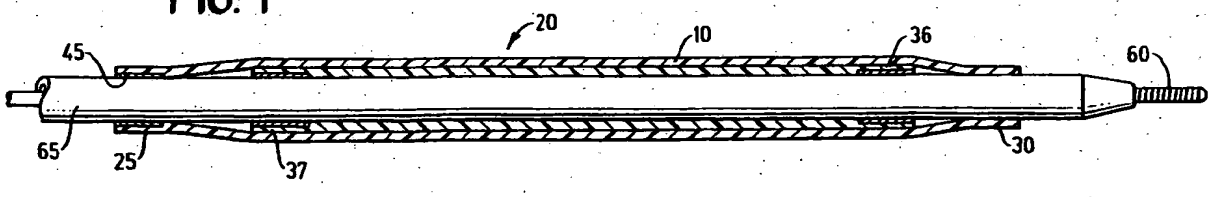
(54) Protective membrane for stent-carrying ballon catheter.

(57) A reinforcing membrane in the form of an elastic sheath used with a balloon catheter to enhance the delivery of an intravascular stent of the kind delivered by a balloon catheter. The sheath (20) is interspaced between the balloon and the stent in the preferred embodiment. The sheath (20) acts as a protective barrier, provides for uniform expansion of the stent, decreases the deflation time of the balloon, prevents undesirable flattening of the balloon upon deflation and withdrawal, and, among other things, provides a friction substrate for the stent. The sheath (20) may be made into an elastic membrane (10) that is applied on the inside or around the outside the balloon. The sheath may be formed of multiple co- extruded layers, with an outermost elastic layer. Preferably the sheath (20) is tubular and attached with adhesive, shrunk fit, or mechanically fastened to the outside of the balloon portion (35) of the catheter. The sheath (20) may contain a radiopaque material that may also be used to indicate when the stent has been expanded to a proper operational diameter.

FIG. 1



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The invention relates generally to an elastic or expandable covering for a balloon or dilatation catheter of the kind used, for example, in percutaneous transluminal coronary angioplasty (PTCA) procedures.

In typical PTCA procedures, a guiding catheter is percutaneously introduced into the cardiovascular system of a patient through the brachial or femoral arteries and advanced through therein until the distal end thereof is in the ostium of the desired coronary artery. A guidewire and a dilatation catheter having a balloon on the distal end thereof are introduced through the guiding catheter with the guidewire sliding within the dilatation catheter. The guidewire is first advanced out of the guiding catheter into the patient's coronary vasculature and the dilatation catheter is advanced over the previously advanced guidewire until the dilatation balloon is properly positioned across the lesion. Once in position across the lesion, the flexible, expandable, preformed balloon is inflated to a predetermined size with radiopaque liquid at relatively high pressures (e.g., greater than about 4 atmospheres) to radially compress the atherosclerotic plaque of the lesion against the inside of the artery wall and thereby dilate the lumen of the artery. The balloon is then deflated to a small profile, so that the dilatation catheter can be withdrawn from the patient's vasculature and blood flow resumed through the dilated artery.

In angioplasty procedures of the kind referenced above, there may be restenosis of the artery, which either necessitates another angioplasty procedure, a surgical bypass operation, or some method of repairing or strengthening the area. To prevent restenosis and strengthen the area, a physician can implant an intravascular prosthesis for maintaining vascular patency, called a stent, inside the artery at the lesion. The stent is expanded to a larger diameter, often by the balloon portion of the catheter. Stents delivered to a restricted coronary artery, expanded to a larger diameter by a balloon catheter, and left in place in the artery at the site of a dilated lesion are shown in U.S. Patent Nos. 4,740,207 (Kreamer) and 5,007,926 (Derbyshire).

The present invention is directed to an elastic or expandable membrane suitable for covering the balloon of a catheter and aiding in the delivery of a stent by the inflation of the balloon portion of a dilatation catheter. The present invention is not limited, however, to PTCA procedures, but has broader applications, and can be used with any type of stent delivered to any vessel or lumen.

This invention is directed to an elastic or expandable membrane that reinforces the balloon portion of a dilatation catheter. The catheter with the reinforced balloon portion is then made more suitable for delivery of a stent. Preferably the membrane is interspaced between the balloon and the stent, in the form of an elastic tubular sheath affixed to the outside of the balloon.

There are several problems associated with balloon catheter delivered stents that are alleviated with the present invention. In one embodiment of the present invention, the membrane, by being between the stent and the balloon portion of the catheter, prevents puncture of the balloon by any protuberance or irregularity found on the stent.

Furthermore, the membrane may be (but is not necessarily) elastic, and the elastic membrane allows the stent to be expanded in a uniform manner. The elastic membrane distributes forces evenly over a larger area, so that a portion of a stent less resistant to radial forces will not expand more than a more resistant portion, as is sometimes the case.

In addition, the membrane prevents damage to artery walls in the event the balloon develops a leak, which causes high pressure fluid to escape through the leak, known as "pin-holing." The membrane would form a protective barrier to minimize the harmful effects of pin-holing in the event the balloon is punctured.

Yet another advantage of the present invention is that when the membrane is made of an elastic material it provides a substrate for the stent, so the stent can be secured onto the balloon in a more positive manner. The membrane provides a cushion in which the stent can dig into, and provides more friction for the stent than the slippery surface of a balloon, which may be covered with an anti-friction material such as Microglide™ coating, marketed by Advanced Cardiovascular Systems, Inc., (ACS) of Santa Clara, California.

Another advantage of the present invention is that it allows for a decrease in deflation time when the balloon is deflated, after the stent is in place. The membrane, in one embodiment being made of an elastic material, reduces the deflation time by squeezing the balloon so it will deflate faster.

Yet another advantage is that the membrane ensures that the balloon will be deflated into a uniform, round balloon, and not into an undesirable flat or pancake form, known as "balloon winging." Balloon winging is undesirable because it increases the likelihood that the balloon will entangle when it is withdrawn from the stent and through the coronary arteries.

A further advantage of the membrane of the present invention is to prevent the "dog bone" shape that stents are sometimes expanded into by a balloon catheter, when not using the membrane of the present invention, which results when there is less resistance to the expansion of a stent at its ends than in its middle. The membrane of the present invention, being preferably longer than the stent, would provide increased resistance to the

radial forces applied to the ends of a stent, allowing the stent to expand in a uniform manner.

Yet another advantage of the membrane of the present invention is that the membrane can be impregnated or made with a radiopaque material so that it may be visible during the angioplasty procedure. This would greatly facilitate the placement of stents, which may otherwise be invisible to the fluoroscopy techniques used in angioplasty.

Still another advantage of the present invention is that a radiopaque marked membrane can indicate whether or not a stent has been expanded to the proper enlarged diameter.

Furthermore, the membrane may be coated or impregnated with a therapeutic agent to provide a localized drug delivery system.

These and other advantages of the invention will become more apparent from the following detailed description thereof when taken in conjunction with the accompanying drawings:

FIG. 1 is an axial cross-section of one embodiment of the present invention in the form of an elastic membrane outside the balloon portion of a catheter and catheter shaft, in the deflated state of the balloon catheter;

FIG. 2 is an axial cross-section of the elastic membrane of FIG. 1 in its inflated state;

FIG. 3 is a cross-sectional view along the diameter of another embodiment of the elastic membrane, employing several layers.

As shown by Figs. 1 and 2, there is shown a first preferred embodiment of the present invention, consisting of an elastic, resilient, membrane layer 10, that forms a sheath or sleeve 20 over the balloon. The membrane layer 10 may be formed of any suitable material that is elastic and resilient. The material preferably is one that has a high degree of linearity (non- plasticity) for a wide range of stress and strain values. In the preferred embodiment, however, any elastic material may be used. Commercially available tubing such as "C-Flex" tubing may be used. "C-Flex" tubing may be obtained from Concept Polymer Technologies of Largo, Florida. In addition, the material should have good tear strength to prevent fracturing or splitting when it is stretched. Suitable materials include silicones, latexes, urethanes, polysiloxane modified styrene-ethylene/butylene-styrene block copolymers (SEBS) and their associated families.

While it is envisioned that in the preferred embodiment of Fig. 1 an elastic material would be used to maximize the benefits of the present invention, it is contemplated that any material could be used, including materials such as the type used to form the balloon portion of a PTCA catheter, like PE-600, a polyethylene based material marketed by Advanced Cardiovascular Systems, Inc. (ACS) of Santa Clara, California. Such materials would be expandable but would not necessarily have to be resilient, as is the material contemplated in the preferred embodiments shown in Figs 1 and 2. Thus, as is known in the art, materials that constitute the balloon portions of PTCA catheters are expandable from one diameter to a larger predetermined diameter, being preformed to expand to the larger diameter, but are not necessarily elastic or resilient.

The material forming the membrane may also be impregnated with a radiopaque marker material, or made with a radiopaque material. Suitable radiopaque materials include iodine based materials and barium salts, including materials containing iodipamide (sold commercially under the trade name Cholografin), iopanoic acid (sold under the trade name Telepaque), barium sulfate, bismuth trioxide, bismuth oxychloride, or powdered metals, such as tantalum.

It is further envisioned that the radiopaque materials in the protective membrane could serve not only to mark the location of the stent in a vasculature, but also to indicate whether or not the stent has been fully expanded to the operational, enlarged diameter at which the stent is properly secured to the body lumen. In conventional expandable stents it is difficult to ascertain when the stent is fully expanded to its operational, enlarged diameter form. Consequently there is always the possibility the stent is under or over expanded. Most stents expanded by balloon catheters rely on the assumption that when the balloon is fully expanded, the stent will by definition be expanded to the proper operational diameter. However, this may not always be the case. It is envisioned that the protective membrane of the present invention, when containing radiopaque materials, could serve as a visual indicia to indicate when the overlying stent is expanded to its proper operational diameter. This could be accomplished by impregnating or forming the membrane with just enough radiopaque material so that the membrane is only visible to fluoroscopy techniques when the membrane is in a non-operational state, at a diameter less than its proper operational diameter. The membrane would disappear from detection by fluoroscopy when it is fully expanded to the point where the overlying stent would be in its operational, enlarged diameter form. This phenomena can be understood as a consequence of the fluoroscope being able to detect only a certain threshold density of radiopaque material, with density measured in terms of either mass or volume of radiopaque material to surface area of membrane containing such radiopaque material. When the membrane has a radiopaque density greater than or equal to the threshold the fluoroscope will detect the membrane, but when the density diminishes, such as when the mem-

brane is expanded and its surface area is increased, the fluoroscope will not be able to detect the membrane, and the membrane will disappear from view on the fluoroscope. By varying the amount of radiopaque material in the stent it is possible to achieve a particular density at which the membrane will disappear from view when the membrane is expanded to a diameter at which the overlying stent is in its operational, properly expanded form. Thus a physician would know that when the radiopaque membrane disappears from view the stent overlying the membrane is at or close to its proper operational diameter, and further expansion of the stent can cease.

As shown in Fig. 2, the membrane layer 10, in the form of a tubular sheath 20 having a proximal end 25 and a distal end 30, surrounds the outside of the balloon portion 35 of a PTCA catheter. Tubular sheath 20 is affixed by adhesive to the catheter at a portion 45 of the catheter shaft or outer member 65, with portion 45 lying at proximal end 25 of the tubular sheath and lying outside the balloon portion 35 of the catheter, which has a proximal portion 37. The balloon portion is affixed to the catheter shaft at proximal portion 37, as is known per se in the art.

It can be seen how sheath 20 entirely overlies and covers the underlying balloon portion 35 of the PTCA catheter. As is known in the art, the balloon portion 35 of the catheter is either bonded to the outer member 65 in an integral manner as shown, or is made one-piece with the outer member. The catheter balloon can be inflated by radiopaque fluid from an inflation port (not shown) extending from a lumen contained in the catheter shaft, or, by other means, such as from fluid communication from a passageway formed between the outside of the catheter shaft and the membrane forming the balloon, depending on the design of the catheter. The details and mechanics of balloon inflation vary according to the design of the catheter, and are known in the art per se.

The balloon portion 35 has a distal end 36 and a proximal end 37 which are both completely covered by tubular sheath 20. As can be seen from the drawings the tubular sheath 20 is affixed to the catheter shaft at portion 45 at a point proximal to proximal end 37 of balloon portion 35, so that the tubular sheath overlies the entire balloon portion of the catheter.

As is shown in the figures, the catheter has an axially extending catheter shaft or outer member (outer lumen) 65, which passes over a guidewire 60. The membrane is adhered to the catheter outer member at a point 45 proximal to the balloon portion of the catheter, rather than distal to the balloon portion, because, in the event of a rupture, the membrane will be fastened at the end upstream from the location of the tear, and thus prevent the membrane from curling or bunching when the catheter is withdrawn. The distal end of the membrane is not secured. This allows for the passage of inflation fluid distal to the balloon in the event of a balloon rupture, through a vent (not shown) in the distal end of the catheter.

Although in the figures the membrane of the present invention is used with an over-the-wire balloon catheter, it may also be used with any other type of catheter, including fixed wire balloon catheters.

Furthermore, the membrane may be adhered to the catheter not only by adhesive, but also by mechanical means. To this end, the membrane may be adhered by mechanical means that include fasteners made of radiopaque material, such as radiopaque stripes around the proximal end of the membrane, to better define the outer limits of the sheath to a fluoroscope.

Alternatively, the membrane may be placed over the balloon portion without the use of adhesives or mechanical means. Thus it is possible to shrink fit the membrane over the balloon portion, with or without the use of adhesives. For example, one method of shrink fitting the elastic membrane onto a PTCA catheter proceeds as follows: A silicon tube with an inner diameter slightly smaller than the shaft diameter of a catheter is attached to the catheter shaft proximal to the balloon by first immersing the silicone tubing into a Freon™ bath. The silicone absorbs the Freon™ readily and swells in addition to softening. Because of the swelling, the inner diameter of the silicone tubing increases, allowing the tubing to slide over the balloon portion of the catheter. As the Freon™ evaporates from the silicone, the tubing shrinks back to its original dimensions. In doing so, a shrink fit is created between the silicone tubing and the catheter shaft proximal to the balloon.

In addition, it is possible to slide the tubing over the balloon after immersing the tubing in alcohol. It is possible that the alcohol may dissolve some of the lubricating coating often found on a dilatation catheter shaft, such as a Microglide™ Coating, manufactured by Advanced Cardiovascular Systems (ACS) of Santa Clara, California. The alcohol lubricates the sheath during the assembly process, then evaporates readily.

After securing the elastic membrane to the dilatation catheter, a stent is positioned over the membrane. The stent is typically about 15 mm long, while the membrane underneath it would be about 20 mm long. In general, membrane 10 is longer than the balloon portion 35. These dimensions, however, are merely representative and are not meant to be limiting.

The stent is positioned over the membrane and balloon portion of the dilatation catheter and gently crimped onto the membrane, which overlies the balloon, either by hand or with a tool, such as a pliers. The membrane provides a cushion or substrate in which the stent can imbed, to further help secure the stent onto the membrane and thus the balloon portion of the catheter. The elastic membrane may be made of a high coefficient of friction material to help the stent hold onto the balloon portion. The balloon catheter is then advanced through and positioned in a patient's vasculature, so that the stent is adjacent to the portion of the vessel where treatment is to take place. The balloon is inflated along with the elastic membrane to expand the stent to an enlarged diameter. During expansion, the sheath provides all of the aforementioned benefits, such as protecting the balloon from rupture, preventing pin- hole effects, preventing distortion of the stent into a "dog bone" shape, providing even expansion of the stent, and securing the stent from axial movement. When the stent has reached the desired diameter, the balloon is deflated. The elastic membrane during deflation provides the aforementioned benefits of reducing deflation time, allowing the balloon to collapse in a uniform manner and preventing the balloon from assuming a "pancake" shape.

In the preferred embodiment, the elastic membrane of the present invention is designed to lie underneath a stent and over the outside of the balloon catheter. The membrane layer is preferably longer than the stent that covers it, so that the ends of the stent may be uniformly expanded. In addition, the membrane layer may have an inner diameter slightly smaller than the outer diameter of a deflated balloon of a PTCA catheter that the membrane layer overlays, when the diameter of the membrane is measured in its natural state, that is, the state prior to the membrane being fitted over the outside of the deflated balloon of the PTCA catheter. As can be seen from the drawings, the elastic membrane layer expands along with the balloon portion of the PTCA catheter, and is interspaced between the balloon portion and the stent.

Though in the preferred embodiment the elastic material is shown in a tubular shape, the elastic material may also be applied in a band or strip form, to surround the balloon portion of the catheter as a winding. Thus the elastic material may be wound around the balloon portion of the catheter, to form an additional, reinforcing layer to the balloon.

Furthermore, although in the preferred embodiment of Figs. 1 and 2 the elastic membrane is shown as affixed adhesively to the outside of the balloon catheter as a separate entity in the form of a tubular sheath overlaying the balloon, it is also contemplated that the elastic membrane may be totally integrated in a one-piece manner with the catheter. To this end, it is also contemplated that the membrane could be laminated onto the material comprising the balloon of a PTCA catheter, either on the outside surface or even the inside surface of the balloon, to reinforce the balloon. If the elastic membrane is placed on the inside of the layer of material forming the balloon, it would not directly contact the stent, however, many of the benefits attained when the elastic membrane is on the outside of the balloon would still be realized.

Furthermore, the elastic material may be deposited or coated chemically onto the balloon portion, on either the inside or the outside surface.

Turning to Fig. 3, there is shown another embodiment of the sheath of the present invention employing multiple layers of material. An inner layer 82 and an outer layer 84 are co-extruded together to form a multi-layered sheath. Inner layer 82 may be made of an inelastic but expandable material such as PE, PE-600 or PET, while outer layer 84 may be an elastic material, such as C-Flex. There may also be more than two layers, in any order of layering, but preferably the elastic layer(s) overlie the inelastic layer(s).

In addition, as before, in any of these embodiments any suitable material could be utilized for the membrane, including the same material that constitutes the balloon portion of a catheter. Furthermore, although the preferred use of the balloon reinforcement of the present invention is for facilitating the delivery of a stent by a balloon catheter, the reinforced balloon catheter may be used for other uses as well.

Other modifications can be made to the present invention by those skilled in the art without departing from the scope thereof.

Claims

1. A stent delivery system for delivering a stent having an expanded position and a collapsed position of the type used in conjunction with a balloon dilatation catheter to reinforce or repair a vasculature, said stent delivery system comprising:

   a balloon dilatation catheter with an elongated tubular member having a proximal and distal end, said tubular member having an inflation lumen extending therein;

   a flexible, relatively inelastic balloon located proximal the distal end of said tubular member, said balloon having a distal end and proximal end attached to said tubular member, said balloon having an outer surface coated with a low coefficient of friction material and an inflation means in communication with said bal-

loon whereby said balloon may be inflated and deflated;

a tubular sheath disposed about said balloon between said balloon and said stent, said tubular sheath having a distal end, proximal end and central portion, said central portion of tubular sheath having an inner surface coated with a low coefficient of friction material and an outer surface coated with a high coefficient of friction material, said tubular sheath secured to said balloon dilatation catheter;

said outer surface of balloon and said inner surface of said tubular sheath forming a substantially frictionless interface permitting said central portion of said tubular sheath to expand substantially without friction upon balloon inflation and translating uneven radial force created by asymmetrical balloon inflation into uniform radial force upon said collapsed stent, forcing symmetrical expansion of said stent and thereby proper stent installation in said vasculature; and

said collapsed stent releasably secured to said high friction outer surface of said tubular sheath thereby retaining said stent on said sheath while said stent is advanced through the vasculature until said collapsed stent is expanded and released at the point of its installation within said vasculature.

2. The stent delivery system of claim 1, wherein said tubular sheath comprises an elastic membrane with an axial length greater than the axial length of said stent.

3. The stent delivery system of claim 1, wherein said tubular sheath comprises an elastic membrane which uniformly expands when said balloon is expanded.

4. The stent delivery system of claim 1, wherein said tubular sheath has an inner diameter defined as its diameter when said tubular sheath is in a collapsed state prior to being fitted over the outside of said balloon, said inner diameter of said tubular sheath is less than the outer diameter of said balloon, when said balloon is in its deflated state.

5. The stent delivery system of claim 1, wherein said tubular sheath is formed of a material selected from the group consisting of silicone, latex, polyethylene or derivatives thereof.

6. The stent delivery system of claim 1, wherein said tubular sheath is adhesively secured to said balloon dilatation catheter.

7. The stent delivery system of claim 1, wherein said tubular sheath is secured to said balloon dilatation catheter by shrink fitting.

8. A method of delivering a stent having an expanded position and a collapsed position of the type used in conjunction with a balloon dilatation catheter to reinforce or repair a vasculature using a stent delivery system, said delivery system, including a balloon dilatation catheter with an elongated tubular member having a proximal and distal end, said tubular member having an inflation lumen extending therein; a flexible, relatively inelastic balloon located proximal the distal end of said tubular member, said balloon having a distal end and proximal end attached to said tubular member, said balloon having an outer surface coated with a low coefficient of friction material and an inflation means in communication with said balloon whereby said balloon may be inflated and deflated; an elastic tubular sheath disposed about said balloon between said balloon and said stent, said tubular sheath having a distal end, proximal end and central portion, said central portion of tubular sheath having an inner surface coated with a low coefficient of friction material and an outer surface coated with a high coefficient of friction material, said proximal and distal ends of said tubular sheath secured to said proximal and distal ends of said tubular body to allow said central portion of said tubular sheath to expand and contract substantially without friction upon balloon inflation and deflation; and means to releasably secure said collapsed stent to provide a high friction contact between said collapsed stent and said high coefficient of friction outer surface of said tubular sheath thereby allowing said stent to be advanced into the patient's vasculature until said stent is expanded and released at the point of its installation within said vasculature, the method comprising the steps of:

percutaneously introducing the stent delivery system, having said balloon, said tubular sheath and said stent in the collapsed position, into the vascular system with the inflation means extending outside the body;

advancing the stent delivery system within the vascular system to the location of said vasculature to be reinforced or repaired;

inflating said balloon with inflation means to uniformly expand said tubular sheath as a result of the substantially frictionless interface between said outer surface of said balloon and said inner surface of said tubular sheath, thereby radially expanding the stent uniformly to

optimize its installation in the wall of said vasculature, and at the same time release the stent from said outer surface of said tubular sheath;

deflating said balloon thereby allowing said tubular sheath to return to its collapsed position around said balloon while leaving said expanded stent installed in said vasculature wall; and

withdrawing said stent delivery system from the vascular system.

9. An improved stent delivery system employing a tubular sheath for delivering an intravascular stent having a collapsed and expanded position for repairing or reinforcing a vasculature, the stent delivery system having a balloon dilatation catheter with an inflation means and a flexible, relatively inelastic balloon adapted to receive inflation fluid from the inflation means, an outer surface of said balloon being coated with a low coefficient of friction material and means to releasably secure said stent to the stent delivery system until said stent is released at the point of its expansion and installation within the vasculature, wherein the improvement comprises:

(a) an elastic tubular sheath having an inner surface and an outer surface, said inner surface of said sheath being coated with a low coefficient of friction material and said outer surface of said sheath being coated with a high coefficient of friction material;

(b) said outer surface of said balloon and said inner surface of sheath forming a substantially frictionless interface thereby permitting said sheath to expand substantially without friction upon balloon inflation and thereby translate uneven radial force created by asymmetrical balloon inflation into uniform radial force upon said collapsed stent, resulting in symmetrical expansion of said stent and thereby proper stent installation in said vasculature; and

(c) said collapsed stent releasably secured to said high friction outer surface of said tubular sheath thereby retaining said stent on said sheath while said stent is advanced through the vasculature until said collapsed stent is expanded and released at the point of its installation within said vasculature.

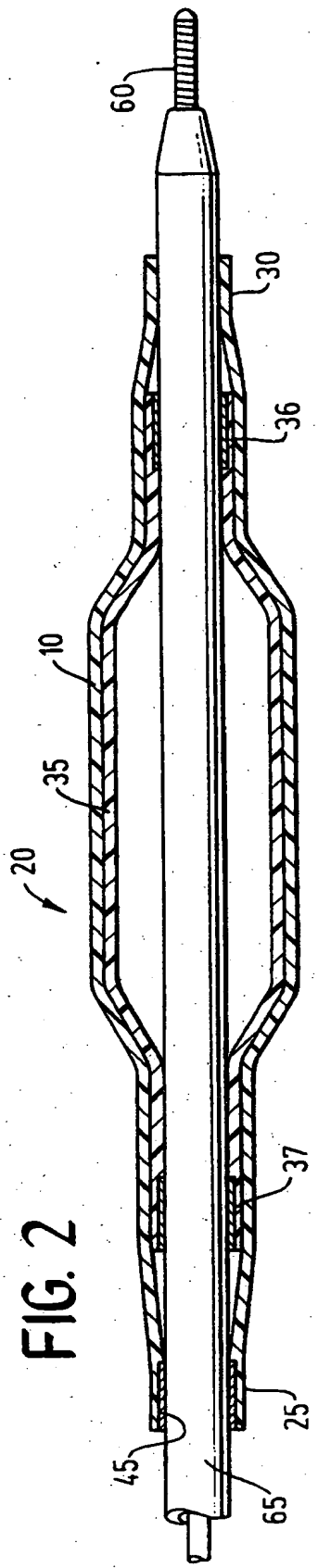

FIG. 2

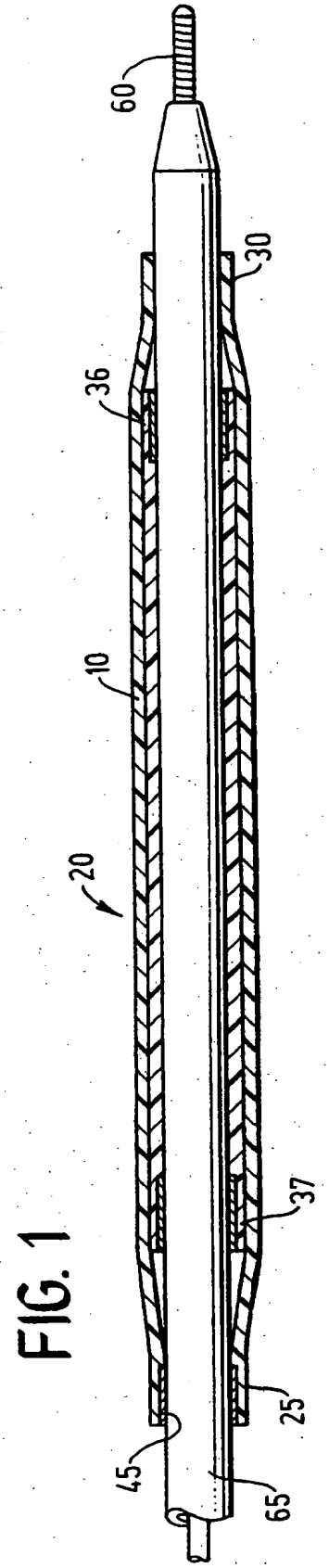

FIG. 1

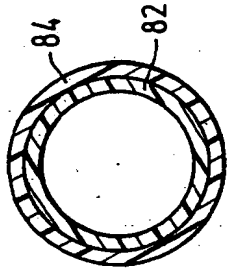

FIG. 3

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 93 30 0160

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
A	EP-A-0 461 474 (KALTENBACH) * abstract; figures *	1-9	A61F2/06 A61M25/10
A	EP-A-0 292 587 (STRECKER) * abstract; figures *	1-9	
A	EP-A-0 428 479 (SCHNEIDER (EUROPE) AG) * abstract; figures *	1-9	
			TECHNICAL FIELDS SEARCHED (Int. Cl.5)
			A61F A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	21 MAY 1993	MIR Y GUILLEN V.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
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